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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/284,155 07/14/99 LOFFLER

J WWH-188

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HM12/0501

EXAMINER

FORMAN, B

ART UNIT PAPER NUMBER

1655

10

DATE MAILED:

05/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/284,155	LOFFLER ET AL.	
	Examiner BJ Forman	Art Unit 1655	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). 			
Status			
<p>1)<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>20 March 2000</u>.</p> <p>2a)<input checked="" type="checkbox"/> This action is FINAL. 2b)<input type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>			
Disposition of Claims			
<p>4)<input checked="" type="checkbox"/> Claim(s) <u>10, 12-25 and 27-30</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) _____ is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input checked="" type="checkbox"/> Claim(s) <u>10, 12-25, 27-30</u> is/are rejected.</p> <p>7)<input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8)<input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>			
Application Papers			
<p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.</p> <p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved.</p> <p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>			
Priority under 35 U.S.C. § 119			
<p>13)<input checked="" type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).</p> <p>a)<input type="checkbox"/> All b)<input checked="" type="checkbox"/> Some * c)<input type="checkbox"/> None of the CERTIFIED copies of the priority documents have been:</p> <p>1.<input type="checkbox"/> received.</p> <p>2.<input type="checkbox"/> received in Application No. (Series Code / Serial Number) _____.</p> <p>3.<input type="checkbox"/> received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p>			
<p>* See the attached detailed Office action for a list of the certified copies not received.</p>			
<p>14)<input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).</p>			
Attachment(s)			
<p>14)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>15)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>16)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.</p>		<p>17)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____.</p> <p>18)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>19)<input type="checkbox"/> Other: _____.</p>	

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DETAILED ACTION

1. Applicant's response filed 20 March 2000 in Paper No.9 is acknowledged. The amendments have been entered as requested. Objections to the specification have been mooted by amendment. Rejections of Claims 1-22 & 25-26 under 35 U.S.C. 112, second paragraph, rejection of Claims 1,2, & 4 under U.S.C. 102(b) and rejection of Claims 1-5, 11 & 26 under U.S.C. 103 are mooted by amendment. Applicant's arguments have been fully considered but are deemed mooted by the claims amendments and cancellations.
2. Claims 1-9, 11 and 26 have been canceled and new Claims 27-30 have been entered.
3. Claims 10, 12-25 and 27-30 are pending and under prosecution.
4. New grounds for rejection are discussed below.

Claim Objections

5. Claim 29 is objected to because of the following informalities: Line 10 of Claim 29 lacks proper noun-verb agreement in the recitation "probes for step b) is". Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
7. Claims 23 & 24 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See

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for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 15-20, 23-24 & 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 15-22 are indefinite in the recitation "from the Sequence Listing" because the SEQ ID NO: occur elsewhere in the specification and therefore the limitation to "Sequence Listing" is confusing and superfluous. It is suggested that the claims be amended to delete "from the Sequence Listing".

b. Claims 23 & 24 provides for the use of nucleotide sequences as hybridization probes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It is suggested that the claims be amended to recite method steps or to depend from a method claim e.g. The method of Claim 27 wherein the primes are SEQ ID NO: 1 and 2 and the probes are SEQ ID NO: 5 and 6.

Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter the claims encompass

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as well as make clear the subject matter from which others would be precluded. *Ex parte Erlich*, 3 USPQ2d 1011 at 6.

c. Claims 27-30 are indefinite in line 8 for the recitation “detects azole derivative-resistant cells” because “azole derivative” lacks proper antecedent basis in the preamble of the claims. It is suggested that the claims be amended to provide proper antecedent basis.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 10, 12-24 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (Antimicrobial Agents & Chemotherapy, July 1997 41(7):1488-1494) in view of Lai et al. (Nucleic Acids Research, 1989, 17(2): 804).

Regarding Claims 10, 12-24 and 27-30, White teaches a method for detecting azole-resistant fungal cells the method comprising the steps of extracting fungus-specific nucleic acids (page 1490, left column, fourth full paragraph, lines 2-5), hybridization of fungus-specific nucleic acid probes (page 1489, Fig. 1a, probes 1-6) to the extracted nucleic acids (page 1490, left column, third full paragraph and page 1491, Fig. 3), wherein the detection of hybridized probes detects azole derivative-resistant cells (page 1492, Fig. 5), wherein the hybridization probes are directed against a DNA segment from the 14- α -lanosterol demethylase gene i.e. ERG16 (page 1489, Fig. 1a), wherein segments of ERG16 are PCR amplified before hybridization with the fungus-specific nucleic acid probes (page 1489, right column, “PCR-

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SSCP analysis" and page 1491, Fig. 3), wherein the hybridization probes comprise the nucleic acid sequences SEQ ID NO: 5,6,7 & 8 (page 1489, Fig. 1a), wherein the PCR amplification primers comprise the nucleic acid sequences SEQ ID NO: 1, 2, 3, & 4 (page 1490, third full paragraph) and wherein the hybridization was performed according to standard published methods (page 1490, left column, fourth full paragraph). White teaches nucleic acid probes and primers comprising overlapping regions of the entire ERG16 coding region. Applicant claims ERG16-specific nucleic acid probes and primers comprising SEQ ID NO: 1, 2, 3, 4, 5, 6, 7 & 8. However, the probe and primer teaching of White comprises the claimed SEQ ID NO: 1, 2, 3, 4, 5, 6, 7 & 8 (page 1489, Fig. 1a). White teaches the allelic variation, R467K (page 1492, right column, first full paragraph) and White teaches that allelic variations occur in all regions of the ERG16 gene (page 1492, right column, last 5 lines). White teaches how to make and use primers and probes for amplifying and detecting specific regions of the ERG16 gene (page 1489, right column and Fig. 1). The nucleic acid sequence of the EFG16 gene was known in the art as taught by Lai et al. who also teach that *Candida albicans* is the major fungal pathogen of humans (page 804 first line and Fig. 1). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of White with the teaching of White and Lai et al. to obtain the claimed invention because one of ordinary skill in the art would have been motivated with a reasonable expectation of success to make primers and probes to the ERG16 gene as taught by White to regions of the ERG16 gene taught by Lai et al. as claimed. Specifically, the skilled practitioner would have been motivated to detect other regions of the ERG16 gene by PCR amplification followed by probe detection for the expected benefit of identifying azole-resistant fungal pathogens in a clinical sample in view of the White teaching that azole resistance in the *C. albicans* is an emerging problem in the HIV-infected population (see Abstract, lines 1-2).

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12. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over White (Antimicrobial Agents and Chemotherapy, 1997, 41(7): 1488-1494) in view of Stratagene catalogue (1988, page 39). White teaches the method for detecting azole derivative-resistant fungal cells wherein the fungal nucleic acids are extracted, amplified with ERG16-specific primers and hybridized with ERG16-specific probes (page 1489 to 1490, left column). White teaches the reagents for performing the method, but White does not teach the reagents combined into a kit. Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method of White into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. 2) The other service provided in a kit is quality control" (page 39, column 1).

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

14. No claim is allowed. Applicant may be able to overcome the above stated rejections over White by submitting a translation of the German priority document dated 22 October 1996.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
April 28, 2000

S. Blomer
SIEPMANN - FORMAN
APR 28 2000